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About Wysa

Wysa is a **chatbot** that helps people deal with **depression, stress, anxiety, sleep and manage mental health**

Wysa's Achievements

Wysa is a cutting edge AI guided empathetic chatbot that is a global tech leader in mental health

Scaling Mental Health for Millions

Purely organic; no marketing spend



Investors



Partners



Role & Responsibilities

Role: Full-Time

Title: Regulatory Affairs Associate

Location: Remote

Responsibilities will include:

1. Support compliance and maintenance of Quality Management System (QMS)
2. Support establishment of risk management practices for medical devices.
3. Support compliance and maintenance of Software Development Life cycle practices with product and technical teams.
4. Work with other various Wysa functions including with external consultants and notified bodies towards certification readiness.
5. Organize and maintain technical documentation and records, including preparing technical files/dossiers for US FDA 510 K, UK MHRA or EU MDR.
6. Support activities related to Clinical Evaluations compliant to regulatory requirements.
7. Review device labeling and advertising claims for compliance with regulations;
8. Participate in internal assessment and audits.
9. Participate in external assessment and audits.
10. Manage non-conformance, corrective action and preventive actions and remediation.
11. Establish effective processes for handling CAPA resulting from customer complaints / feedback
12. Conduct required regulatory training to all staff and monitor training coverage and effectiveness.
13. Support the development of new and modified regulatory affairs procedures.
14. Assists in the maintenance and organization of regulatory records.
15. Developing dashboards, metrics, and reports for communication to management. Other duties as assigned.
16. Maintain the Confidentiality, Integrity and Availability of all information or assets shared and assessed by you
17. Adhere to Wysa's security, privacy and compliance policies and procedures
18. Contribute to building continual improvement practices

Qualifications & Skills

1. 1-2 years of relevant medical device quality/regulatory capacity.
2. Bachelor's or master's degree
3. Experience in regulatory affairs related to software-based medical devices.
4. Experience with process verification and validation
5. Familiarity with regulatory requirements in major international markets
6. Ability to learn quickly, work independently, and maintain professional skepticism
7. Ability to work in a fast paced or rapidly changing environment
8. Ability to interact with staff from multiple departments.
9. Demonstrated proficiency in MS Office (Excel, Word, PowerPoint) is a must
10. Highly organized and detailed-oriented
11. Excellent communicator
12. Excellent analytical and writing skills

If you are all this with a heart of empathy, it's always a plus.

Why work at Wysa?

Take **ownership** and be an integral part of a **fast-growing startup**. You will build valuable skills as a professional while also making friends for life

Get a chance to work closely on the latest tech offered by Apple, by attending events hosted by Apple. Wysa was one of only 10 startups chosen for the [Apple entrepreneur camp in 2019!](#)

We offer **flexible work hours**, a possibility for a **fully remote job** and a culture where you thrive and are rewarded for being a smart worker

Join our team for an exciting, challenging and fulfilling role!

About WYSA's Team

Global Team - The team comprises people from all over the world and is distributed around the world. Expand your horizons by working with a multicultural team

Industry Leaders - The founders and senior team members are from IITs, IIMs, London School of Business and have held top positions across Goldman Sachs, Pearson, Microsoft leading cross-functional global teams. Work with and learn from the very best

Passionate Colleagues - Work with passionate hard-working colleagues who will push the boundaries and only deliver the best

In Their Own Words

I chose to switch my domain to work on AI and WYSA was the best place to start this journey. WYSA's work culture applauds ownership and deliverance while having a learning environment. All of this along with making an impact on the lives of so many makes working at WYSA extremely gratifying.

- Anand Gupta, Data Scientist

Buzzwords

Google funded, VC funded, profitable, has achieved breakeven, global team, global customers, product company, Apple awarded product, Harvard research partner, Google Play Best App of 2020, Made in India, Made for the World

Contact Details!

If you are sold, please fill this [Google Form](#) to apply.